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December 1, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 97N-484S

To Whom It May Concern:

It has come to my attention that the FDA is proposing to change the regulations currently used for the supply of bank bone to use in surgical procedures requiring fusions, etc. This potential FDA change will most likely eliminate the invaluable resource of bank bone to use in cervical fusions and spine fusion cases in the future, Such a change would drastically affect the outcome of healthcare delivered to an alarming number of patients.

I have personally used bank bone for anterior cervical fusions for over ten years and I have never had a single complication related to the use of this material. To put into numbers of patients, this basically would affect approximately 1500 of my own patients personally. If bank bone were not available to these 1500 patients, I would have had to harvest bone from their own hip, which would have required another surgical incision, significant post-operative hip pain, and possible complications, including infection at the donor site and long term complications with hip pain and possible fractures through the hip where the bone was harvested, etc.

It is absurd for me to believe that the FDA would somehow want to change the regulations of the use of bank bone, which has been clinically accepted for decades in the United States, as well as Europe and every other developed country in the world. Since the affects of changing this regulation are overwhelmingly negative towards patients requiring such procedures, I would hope that they would reassess their plan and continue to leave bank bone resources as they are.

I would be happy to talk to any FDA personnel who has specific questions about the use of bank bone and its safety in patient care.

Respectfully,

Lee E. Krauth, M.D.

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